NATIONAL WOMEN'S HEALTH NETWORK

MEMORANDUM

TO: Obstetrics and Gynecology Devices Panel
Center for Devices and Radiological Health
Food and Drug Administration

FROM: National Women's Health Network

RE: Reclassification of Home Uterine Activity Monitor
Docket Number 97P-0350

DATE: October 22, 1999

This memorandum conveys the National Women's Health Network's opposition to the Obstetrics and Gynecology Devices Panel's recommendation to reclassify the home uterine activity monitor (HUAM) from class III to class II.

The Network believes that HUAMs are being used in a context which raises significant safety questions about what might otherwise be a straightforward reclassification decision. The panel has recognized in its discussion of the proposed reclassification that there are significant risks to health posed by off-label use of the device and the multitude of unnecessary interventions that are likely to be initiated following the detection of clinically meaningless contractions by HUAMs. As the Network has noted in previous statements, manufacturers of these devices are promoting them in ways that have created the widely held belief among physicians and consumers that home uterine activity monitors are effective in preventing pre-term births and producing healthier babies, rather than simply as diagnostic devices. These claims and beliefs are not supported by evidence from any well-designed studies. This is a marketplace that is out of control.

The Network believes that the panel's recommendation to reclassify the HUAM from class III to class II fails to adequately take into account the reality of how the device is being promoted and used. This situation demands greater regulation, not less. Although the HUAM might very well meet the safety standards for a class II device if it were being used and promoted as approved, the FDA should not make this decision with its head in the sand. The agency must recognize the real health risks posed by the inappropriate marketing and use of HUAMs and must not take any action that will encourage further unsupported claims and unsafe use.

The Network urges the FDA not to act on the panel's recommendation to reclassify the HUAM from class III to class II. By reclassifying the HUAM into a category with less oversight, the FDA will exacerbate the inappropriate marketing and use of the device.

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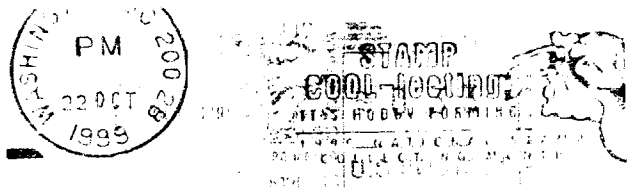

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